

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

DAVID A. REED AND GEORGIA
GERARD-REED,

Civil No. 17-5560 (JRT/HB)

Plaintiffs,

**ORDER ADOPTING REPORT AND
RECOMMENDATION OF
MAGISTRATE JUDGE**

v.

ST. JUDE MEDICAL,

Defendant.

David A. Reed, P.O. Box 346, North Beach, MD 20714, and Georgia Gerard-Reed, 3800 Sixth Street, North Beach, MD 20714, plaintiffs *pro se*.

Steven J. Wells and Vanessa J. Szalapski, **DORSEY & WHITNEY LLP**, 50 South Sixth Street, Suite 1500, Minneapolis, MN 55402-1498, for defendants.

On December 12, 2017, David R. Reed filed a complaint against St. Jude Medical, alleging that a mechanical heart valve David Reed received from St. Jude in 2011 was defective. St. Jude removed the case to federal court, and filed a Motion to Dismiss. On July 24, 2018, Magistrate Judge Hildy Bowbeer issued a Report and Recommendation that the motion be granted and Reed's claim be dismissed with prejudice. (Report and Recommendation at 12, Docket No. 50). The Magistrate Judge also recommended denying Reed's various outstanding motions and filings, because the admission of those motions would be futile in helping Reed establish a valid claim. (*Id.* at 9).

In response, Reed attempted to appeal the Magistrate Judge's Report and Recommendation to the Eighth Circuit. However, because objections to a Report and Recommendation are to be made in the District Court, the Court will construe Reed's attempt to appeal as an objection, and review the Report and Recommendation de novo. Because Reed does not state a claim upon which relief could be granted, the Court will adopt the Report and Recommendation, deny Reed's objections, and grant St. Jude's motion to dismiss.

BACKGROUND

David Reed received a mechanical heart valve from St. Jude Medical on December 13, 2011. (Notice of Removal, Ex. A p.1, Docket No. 1-1). By the end of 2016, however, he began to experience heart and lung complications and eventually suffered a heart attack on December 9, 2016. (*Id.*). One year later, Reed brought this action against St. Jude Medical, claiming that the heart valve was defective and caused his 2016 heart problems. Reed, in support of his allegations, says that several doctors informed him that the valve leaked and needed to be replaced. (*Id.* at 1-2). On December 22, 2017, the heart valve was removed.

The valve at issue had previously been granted Food and Drug Administration ("FDA") approval through the FDA's Premarket Approval ("PMA") process. (Wells Decl. Exs. 1, 2, Docket No. 16). The PMA process was established by the Medical Device Amendments of 1976 as part of an overarching attempt to oversee and regulate the use of new medical devices. 21 U.S.C. § 360c *et seq.* Life sustaining devices—such as the heart valve here—must go through the rigorous PMA process in order to be approved for use in

the market. *See* 21 U.S.C. § 360e. After receiving PMA, a device cannot be changed or altered unless approved by the FDA. *Id.*

After removing Reed's action to this Court, St. Jude filed a Motion to Dismiss. In response, Reed filed a number of motions to admit various exhibits. In some of these exhibits, he seems to allege medical fraud against St. Jude in relation to an off the record heart exam which he claims was for the benefit of St. Jude and which results he was never given. He further argues that the PMA that St. Jude received from the FDA should be invalidated because the FDA did not consider relevant evidence. Finally, Reed moved to admit an Exhibit K, which he argues proves St. Jude's guilt, but which is neither signed nor sworn.

The Magistrate Judge carefully reviewed the record and complaint and issued a Report and Recommendation that St. Jude's Motion be granted and that any outstanding motions by Reed be denied. While the complaint and subsequent filings are difficult to understand, the Magistrate Judge liberally construed them to consider any potential claims they may have contained. The Magistrate Judge concluded that, to the extent that any claim was discernible regarding the alleged heart valve defect, Reed failed to state a claim upon which relief could be granted. The Magistrate Judge further concluded that any potential claim regarding the alleged medical fraud was not adequately pleaded. Finally, the Magistrate Judge recommended that any outstanding motions—which she interpreted as motions to amend the complaint—be denied because they could not help Reed state a plausible claim.

DISCUSSION

In reviewing a complaint under a Rule 12(b)(6) motion to dismiss, the Court considers all facts alleged in the complaint as true, and construes the pleadings in a light most favorable to the non-moving party. *See, e.g., Bhd. of Maint. of Way Employees v. Burlington N. Santa Fe R.R.*, 270 F.3d 637, 638 (8th Cir. 2001) (per curiam). To survive a motion to dismiss, however, a complaint must provide more than “‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action. . . .’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). That is, to avoid dismissal, a complaint must include “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Id.* (internal quotation marks omitted). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

Upon the filing of a Report and Recommendation by a Magistrate Judge, “a party may serve and file specific written objections to the proposed findings and recommendations.” Fed. R. Civ. P. 72(b)(2); *accord* D. Minn. LR 72.2(b)(1). “The district judge must determine de novo any part of the magistrate judge’s disposition that has been properly objected to.” Fed. R. Civ. P. 72(b)(3); *accord* D. Minn. LR 72.2(b)(3). “Objections which are not specific but merely repeat arguments presented to and considered by a magistrate judge are not entitled to de novo review, but rather are reviewed for clear error.” *Montgomery v. Compass Airlines, LLC*, 98 F. Supp. 3d 1012, 1017 (D. Minn. 2015).

Here, because of Reed's erroneous attempt to appeal the Report and Recommendation directly to the Eighth Circuit, it is difficult to determine precisely what objections were made. Reed does seem to specifically object to the exclusion of Exhibit K, and argues that it should be added to the complaint. Beyond that, any other objections made are general in nature, and are therefore procedurally inadequate. *See* Fed. R. Civ. P. 72(b)(2). However, because Reed brought this claim pro se, the Court has carefully reviewed the record and looked at the entire Report and Recommendation de novo.

After review of the Report and Recommendation the Court finds that the Magistrate Judge appropriately concluded that Reed's claims regarding the defective heart valve should be dismissed for failure to state a claim because they are expressly preempted by federal law. *See* 21 U.S.C. § 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008). Additionally, the Court finds that the Magistrate Judge properly determined that any potential claim of medical fraud regarding the off the record heart scan was not sufficiently pleaded and that leave to amend the complaint should be denied. Finally, the Court finds that the Magistrate Judge correctly denied Reed's attempt to amend the complaint by adding Exhibit K, and correctly denied any other outstanding motions, because they could not help Reed state a valid claim for relief. Accordingly, the Court overrules Reed's objections and adopts the Report and Recommendation of the Magistrate Judge.

ORDER

Based on the foregoing and the records, files, and proceedings herein, the Court ADOPTS the Report and Recommendation of the Magistrate Judge dated July 24, 2018.

[Docket No. 50]. Accordingly, IT IS HEREBY ORDERED that:

1. Defendant St. Jude Medical's Motion to Dismiss [Docket No. 11] is
GRANTED;
2. Plaintiffs David Reed and Georgia Gerard-Reed's complaint [Docket No. 1] is
DISMISSED WITH PREJUDICE; and
3. Plaintiffs' Motion to Add Exhibit K [Docket No. 42] is **DENIED.**

LET JUDGMENT BE ENTERED ACCORDINGLY.

DATED: September 6, 2018
at Minneapolis, Minnesota.

s/John R. Tunheim
JOHN R. TUNHEIM
Chief Judge
United States District Court